

### **REMARKS and ARGUMENTS**

This amendment and request for reconsideration is being submitted on November 21, 2003. An office action was mailed on September 24, 2003. A response is due on or before December 24, 2003. Accordingly, this response is timely filed. Applicants request the amendment and arguments submitted herewith be made of record in the instant application.

#### *Claim Status*

Claims 1, 3, 5, 8-12, 20-28 and 30 are pending. Claims 25 and 27 have been amended. Support for this amendment is found in claim 20. Claim 29 has been cancelled. Claim 20 has been amended to place a period at the end of the claim. Claims 1 and 20 have been amended to delete the word "optionally". Support for this amendment is found in the specification as filed and in the claims which recite the inclusion of HA particles. Claim 23 has been amended to insert a space between two words.

No new matter is added by these amendments, and entry is requested.

### **ELECTION/RESTRICTION**

In response to the restriction requirement of paper no. 18, Applicants have cancelled claim 29 without prejudice or disclaimer.

### **PRIORITY**

The Examiner has again denied priority to the provisional application. This issue has been well argued by Applicants, both in telephonic interviews and in previous responses, including the arguments filed with the RCE, said arguments went unanswered. Those arguments are repeated verbatim below. Applicant's request the Examiner to respond to these arguments. Applicant will appeal this issue, so it would be helpful to

the Board of Patent Appeals and Interferences if the Examiner would respond to each and every argument presented below, in the next office action.

The Office Action (paper no. 11, mailed 2/28/2003, paragraph no. 1, denies Applicant's claim for priority to Provisional Application 60/201,556, because allegedly "the provisional application does not provide a specification disclosing the claimed invention, therefore there is no support for the claimed invention." In the telephonic interview conducted between Supervisory Patent Examiner Jones and Charles R. Nold on July 16, 2003, SPE Jones alleged that the provisional application 60/201,556 only had support for the recitation of a glass/Hydroxyapatite mixture of 50/50 weight percent. Further, SPE Jones alleged that the provisional application only had support for the glass/hydroxyapatite layer being the outer layer. No other objections to the specification have been made. Applicants disagree for the reasons set forth below.

The standard for a provisional patent application can be found in MPEP 601 which states that 35 U.S.C. 111(b) mandates the contents of a provisional application specification. 35 U.S.C. 111(b) mandates that a provisional application shall comply with the first paragraph of 35 U.S.C. 112 and include a drawing if necessary. A claim is not required. Applicants assert that the provisional application as filed does provide support for the invention as currently claimed. The Specification is a compilation of six different peer-reviewed publications authored in some instances by inventors of the instant.

Restated, the issue is whether the instant claims complies with 35 U.S.C. 112, first paragraph, i.e. is the invention claimed in the instant invention described and enabled in the specification. Applicants assert that it is. It was alleged that the provisional application only had support for the recitation of a glass/Hydroxyapatite mixture of 50/50 weight percent. Applicants disagree. Applicants assert that there is broad support in the provisional application for the range claimed, which is "up to 50 wt %". Support for the claimed range of glass/hydroxyapatite is found in the provisional application as follows:

1. page 11, col. 1, lines 11-12: "It was possible to fabricate coatings whose external layer had silica contents as low as 53 wt% **or were a mixture f HA particles and glass.** (emphasis added) (note: no mention of the amount of HA, thus an open range)
2. page 12, lines 11-13: "Hydroxyapatite (HA) particles were mixed with the glass powder and the mixture was placed on the outer surface of the coatings to render them more bioactive." (note: no mention of the amount of HA, thus an open range)
3. page 18, col. 1, last paragraph: "The glasses can be used alone or mixed with HA." (note: no mention of the amount of HA)

As the Examiner is of course aware, the test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983). Precisely how close the original description must come to comply with the description requirement of 35 U.S.C. § 112 must be determined on a case-by-case basis: *In re Wilder*, 736 F.2d 1366, 1375, 222 USPQ 369, 372 (Fed. Cir. 1984). There is no per se rule that ranges in claims added in a continuation application must correspond exactly with those disclosed in the parent application. *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F. 2d 1570, 227 USPQ 177 (Fed. Cir. 1985). Accordingly, under *Ralston* it is Applicant's position that the repeated mention in the specification of using a mixture of HA and glass, coupled with a specific example showing a glass/HA ratio of 50/50 is sufficient disclosure to enable and describe the current invention as claimed. Under *In re Kaslow*, the provisional supports the Utility application because it would have been clear to the artisan, upon reading the provisional, that a wide range of HA/glass mixtures are part of the instant invention. This is because the provisional recites, at least in three places as mentioned above, the use of *some quantity* of HA particles in the glass/HA mixture, and also provides a mid-point range of 50/50.

During the interview between SPE Jones and Charles Nold it was also alleged that the provisional application for which priority is sought only discloses and enables a multilayer article for which the HA is located **only** in the outermost layer. Applicants disagree with this position. Support for incorporating HA into the layers as claimed is found in the provisional application as filed as follows: page 2, col. 2, lines 32-34 which recite: "Layered glass coatings with embedded HA particles (<20 $\mu$ m) were also fabricated; in these coatings the final layer was a composite of glass and HA (50/50 wt%)." (note that the provisional recites "layered glass *coatings*, (emphasis added) with embedded HA particles. This means more than one coating, which would inherently mean other than just the outermost coating. Thus Applicants assert that there is indeed support for the claimed invention in the provisional, and withdraw of the objection is requested.

Applicants apply the arguments above to the instant denial of priority. Applicants note that the current rejection (paper no. 18) fails to point out what is deficient in the provisional, but again just says that it is deficient. This rejection is in error and withdrawal is requested.

### **SPECIFICATION**

The Examiner has objected to the amendment filed September 9, 2003 under 35 U.S.C. 132 because it allegedly introduces new matter into the disclosure. No amendment was filed on September 09, 2003. Applicants assume the Examiner means the amendment filed August 28, 2003. Applicants further note that no amendments were made to the specification, but assume that the Examiner is referring to claim 29. The objection not stating otherwise, Applicants will proceed assuming the Examiner meant that there was new matter in the claims. Claim 29 has been cancelled by amendment, thus this objection is moot.

**CLAIM REJECTIONS**

*Claim Rejections- 35 USC § 112*

Claims 25 and 27 have been rejected as allegedly lacking antecedent basis.

Claims 25 and 27, *as amended herein*, do in fact have antecedent basis. Accordingly, withdrawal of the rejection is requested.

*Claim Rejections- 35 USC § 102(b)*

Claims 1, 8 and 23 have been rejected as allegedly being anticipated by Pazo et al., "HA-bioactive glass composites: High temperature reactivity and "in-vitro" behavior", Scripta Materialia, Vol. 34, No. 11, pp. 1729-1733, 1996. Applicants disagree. The rejection states that Pazo et al. disclose a multilayered article comprising a Ti or Ti alloy substrate, and the Examiner points to the text of page 1733 and Figures 6 and 7. In response, Applicants argue that Pazo et al. does not disclose a multilayered article comprising Ti or Ti alloy. The Examiner states that the abstract line 6 teaches claim 8, a substrate using a Ti or Ti alloy. This is incorrect. The abstract line 6 states "This glass combines both high bioactivity and excellent adhesion to Ti and Ti alloys". This does not in fact teach Applicant's claimed multilayer article comprising a metal substrate and Applicant's glass composition. What the sentence does state is the glass composition (BAG) provides both high bioactivity and excellent adhesion to Ti and Ti alloys. The glass composition referred to is found in the previous sentence. The entire purpose of the article is to study the high temperature reactivity between HA and the glass, see pp. 1729, first sentence, last paragraph. The composite being referred to is not a composite of layers, but the mixture of glass and HA, see pp. 1731, paragraph 2, line 4. Figures 6 and 7 do not show multilayered articles in accordance with applicant's invention as the

examiner has alleged, but show the surfaces of both samples (which are BAG +HA mixture) after soaking in SBF for different times. Because the reference does not disclose each and every limitation of Applicant's claims, the rejection is in error, and withdrawal is requested.

Claims 1, 8 and 23 have been rejected under 35U.S.C. 102(b) as allegedly being unpatentable Pazo et al., Silicate Glass coating on Ti-based implants, Acta Matter, Vol. 46, No. 7, pp. 2551-2558, (1998). Applicants traverse this rejection. The claims, *as amended*, require HA in the glass composition. Pazo et al. does not disclose this limitation. Because each and every limitation of the rejected claims is not disclosed in the rejection, the rejection must fail. Withdrawal of the rejection is requested.

Claims 1, 3, 5, 8-12 and 20-28 have been rejected under 35U.S.C. 102(b) as allegedly being unpatentable over Bioceramics: Materials and Applications article titled "Glass-Hydroxyapatite coatings on titanium-based implants", by Gomez-Vega, published February 2000.

Applicants traverse this rejection. The publication referred to in the Office Action was actually published on 2/23/2002, thus it is not prior art under 35 U.S.C. 102(b). Evidence of this publication was previously submitted and made of record, and it is a letter from the Publisher, The American Ceramic Society. The letter states that "the first books being mailed to customers on 2/23/2000.

When the Board of Patent Appeals and Interferences settles the priority question, this issue will be decided as well.

Withdrawal of the rejection is requested.

*Claim Rejections- 35 USC § 103*

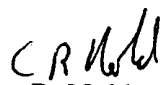
Claim 30 has been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Bioceramics: Materials and Applications article titled "Glass-Hydroxyapatite coatings on titanium-based implants" and further in view of "A multilayer approach to fabricate bioactive glass coatings on Ti alloys", by Gomez-Vega et al. published 1999. Applicants traverse this rejection. As, explained above, the primary reference is not anticipatory under 35 U.S.C.102, and therefore this rejection must fail. The primary reference is the subject of applicant's provisional application, which Applicant's are confident the Board will ultimately grant priority to. Thus this rejection is in error, and withdrawal is requested.

*Conclusion*

Having overcome all rejections, Applicants requests that a timely Notice of Allowance be issued in this application.

All fees believed due have been submitted. If Applicant is wrong in this assumption, the PTO is authorized to charge any deficiency to Applicant's deposit account number 120690. The PTO is not authorized to charge the issue fee to this account.

Submitted,

  
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